UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

TARA J. LOUX, M.D.,

Plaintiff,

v. Case No. 8:21-cv-1891-WFJ-TGW

BAYCARE MEDICAL GROUP, INC.,
ST. JOSEPH'S HOSPITAL, INC.,
and ANAND NAYEE, M.D.,

Defendants.
_____/

ORDER

The Court denies the Motion for Reconsideration and Motion to Stay Production. Doc. 106. The Motion for Reconsideration reargues the points made previously in writing and at the prior hearing. The Motion provides no new grounds, or description of items the Court overlooked or misapprehended previously. The Court reiterates its Order of May 26, 2023, Doc. 103.

The Court does not restate the statutory description of the Patient Safety and Quality Improvement Act and the asserted privilege. *See* 42 U.S.C. §§ 299b-21 - 26 (2005); 42 C.F.R. pt. 3. Sufficient to say, the manner in which Defendants have stored their information, and the blanket of privilege in which they seek to envelope it, would prohibit any civil rights litigant like Plaintiff from ever

discovering appropriate comparators for her case. The description of the items discussed here were reviewed at the prior hearing.[1]

It appears to the Court that the "Category 5" spreadsheets (and the data they represent) were created for multiple uses and are not solely the protected patent safety work product. This information is not prepared and kept solely for provision to a Patient Safety Organization ("PSO"), despite the artful declarations provided.

The first place to examine to determine if this information is put to dual or multiple uses is BayCare's own description of its "Patient Safety Organization" protocol. *See* Doc. 62-1 (Small Decl.) at 11. This describes what BayCare declares the PSO system to be. Under this system "Patient Safety Work Product" ("PSWP") may be provided by the BayCare system for analysis to over a dozen local entities, including First Focus committees, the Board of Directors, Peer Review Committees, Clinical Excellence teams, Root Cause Analysis (RCA)

[1] The specific item under discussion is a thumb drive with a pdf and an excel spreadsheet, for each of the 16 potential comparators. The Court has since reduced this number to ten. This thumb drive is filed under seal with the Clerk. Defendants only need to produce the data for the ten potential comparators that Plaintiff selected.

During the hearings this data set was referred to as "item 5-quality files." Each spreadsheet is titled at the top "Peer Review Summary—All Review Types." The spreadsheets contain incident reports describing various incidents involving potential comparators. For example, the very first entry on the first possible comparator describes a laproscopic appendectomy where a small artery was cut. The second entry discusses an unplanned return to the operating room due to a kink in a catheter. Under "Recommendation" the various cells are blank or may contain various entries such as "Physician Counseling" or "Focused Review," "Track and Trend," etc. "Quality Concerns" may be listed like "Failure to Follow Policy & Procedure" or "Surgical Complications."

teams, Medication Usage and Safety teams, and the like. *Id*. at 12. Beyond these 12 plus recipients, permissible disclosures of BayCare's "Patient Safety Work Product" include providing such work product to: accrediting agencies; grantees, contractors, and researchers sanctioned by "the Secretary;" the Food and Drug Administration; those recipients "the Secretary" or Florida or Federal law deem necessary for business operations and are consistent with relevant goals; and to law enforcement if the discloser reasonably deems it "necessary for criminal law enforcement purposes." *Id*. BayCare thus designates many sources beyond a PSO as possible recipients for its PSWP.

Each item that was produced for *in camera*, *ex parte* review is labeled at the top "peer review." One column called "Review Type" is often populated "peer review." Action columns look like peer review. Nothing visible refers to a PSO or indicates the items are sent to a PSO. Action terms, like "Refer to Committee," "Track and Trend," "Focused Review," or "Physician Counseling" suggest the dual purpose of this data. It is not the "PSO committee" that is referred to here. The PSO does not counsel the physician subject to the counseling. The local Quality Department does the "Track and Trend," not the PSO. *See* Doc. 106-1 (Villareal Aff.) ¶¶ 32–35.

Important to Plaintiff, some of her potential comparators "were required to receive additional education or were counseled about specific cases [and] the

documents that reflect BayCare's record of these decisions are the quality files . . ." *Id*. ¶ 37(a). And possibly two comparators were placed on "Focused Review" (a review not by the PSO) to address surgical issues. *Id*. ¶ 37(d). Plaintiff is entitled to review the matters to prove (if she can) that she was treated disparately than her professional peers, for discriminatory purpose. BayCare's current posture makes her unable to have proper litigation discovery.

The Quality Department of BayCare does submit reports or information related to incidents of individual physicians to the peer review committee of St. Joseph's Hospital. Doc. 74-1 (Small dep.) at 13. This comes out of the rlDatix system discussed here. *Id*.

"Quality of Care" events include other incidents beyond the serious "Code 15" mishaps that must be reported to the Florida Agency for Health Care Administration. *Id*. at 21–22. These non-code 15 events are found in the subject documents that Defendants object to producing. But they are relevant to risk management and various committees across BayCare and within each of the hospitals. *Id*. at 11–13. They certainly would be relevant to Plaintiff if her comparators were treated differently than she.

A specific event could be "tasked through to the quality team for peer review. And dependent on content, it could also be sent through to risk

[management]." *Id*. at 20.[2] Events are entered into the rlDatix systems "related to quality of care" and the quality of care events listed can then be submitted to be reviewed for peer review. *Id*. at 44. The event report may be submitted both to the PSO and to the rlDatix peer review module. *Id*. at 47. And the medical staff department may print out the rlDatix report, and keep it, after peer review. *Id*. at 48. The information continued in the patient safety evaluation system is provided to the peer review committee. *Id*. at 57. The purpose of providing this information is to inform peer review at the hospital. *Id*. The same information from the patient safety evaluation system is provided to the root cause analysis teams. This is not the PSO. These teams are "facilitators who move around the system dependent on future events," where events occurred—interdisciplinary teams brought from several sources such as the President of the facility, the local experts in the hospital system, etc. This has nothing to do with the PSO, but these utilize the data in the patient safety evaluative system. *Id*. at 57–58. Clearly this information serves multiple functions for multiple parties within this large system.

Root cause teams use this system and data. *Id*. at 55–56. Root cause teams are risk management. *Id*. at 20–21. HHS guidance states that information prepared for risk management is not PSWP. *See supra* note 2.

[2] HHS notes that information prepared for risk management is not PSWP. Patient Safety and Quality Improvement Act of 2005—HHS Guidance, 81 Fed. Reg. 32655-01, 32656, 2016 WL 2958759 (May 24, 2016) ("HHS Guidance").

As well as risk management and "several committees of provider and team members," BayCare and St. Joseph's Hospital utilize this data for BayCare and St. Joseph's own peer review. Doc. 62-1 (Small Decl.) at 4, ¶¶ 19–20. So the data is kept for, and used by, entities other than the PSO. This data can be reviewed by the facility, internal committees such as St. Joseph's medical staff peer review committees, BayCare's peer review quality committee, or St. Joseph's "first focus" committee. *Id*. at 7, ¶ 35.

And this data is kept for use in answering outside questions as well. Defendant's witness Villareal stated BayCare may use the claimed-privileged data to conduct analysis to answer questions "[i]f AHCA or any other agency requests information or has any questions regarding a specific event." Doc. 106-1 ¶ 10.

The intent of "the Patient Safety Act is to protect the <u>additional information</u> created through voluntary patient safety activities, not to protect records created through providers' mandatory information collection activities." HHS Guidance at 32655, cited *supra* note 2 (emphasis added). HHS advises that the Act would not prevent medical malpractice patients from obtaining the records about their case that they could have obtained before the Act. *Id*. at 32656. "Nor was the Patient Safety Act intended to insulate providers from demonstrating accountability through fulfilling their external obligations." *Id*. HHS then cites with approval the legislative history that "[t]his legislation does nothing to reduce or affect other

Federal, State or other local legal requirements pertaining to health related information." *Id*. at 32660 n.6.

The Motion to Reconsider, Doc. 106, is denied.

DONE AND ORDERED at Tampa, Florida, on June 27, 2023.

WILLIAM F. JUNG
UNITED STATES DISTRICT JUDGE

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